

PATENT COOPERATION TREATY

(sc. 17.05.05)

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/007889 ✓

International filing date (day/month/year)
15.07.2004 ✓

Priority date (day/month/year)
17.07.2003 ✓

International Patent Classification (IPC) or both national classification and IPC
A61K7/06, A61K7/48, A61K7/50

Applicant
ZSCHIMMER & SCHWARZ ITALIANA S.P.A. ✓

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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10/566030

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2004/007889

IAP20 Rec'd PCT/EP 17 JAN 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/007889

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4,7,10
	No: Claims	1-3,5,6,8,9
Inventive step (IS)	Yes: Claims	
	No: Claims	1-10
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

see form 210

- 1 The following documents are referred to in this communication:
D1 : US 5 843 407 A (LEATHERBURY N. CAMPBELL ET AL) 1 December 1998
D2 : WO 98/09611 A (SEPPIC SA) 12 March 1998
D3 : WO 03/039496 A (ARIOTTO A.; GUALA F. (IT); VILLA G. (IT); MERLO E.) 15 May 2003
D4 : WO 98/29094 A (UCHIYAMA HIROTAKA ; HU FANG (JP); HARADA KIROH (JP); SAKO TAKASHI (JP)) 9 July 1998
- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 to 3, 5 to 6 and 8 to 9 is not new in the sense of Article 33(2) PCT.
 - 2.1 Document D1 discloses (cf. col. 1 line 56 to col. 2 line 11, col. 5 lines 6 to 14, col. 7 line 40 to col. 8 line 13, col. 11 lines 31 to 51, col. 12 lines 34 to 38, col. 16 lines 16 to 18 and Examples VII and VIII) a moisturising lipstick composition containing oily substances, N-amino acid derivatives, which is preferably N-lauroyl glutamic acid dibutylamine or N-stearyl glutamic acid dihexylamide and less than 1% water.

Actually, the presence of surfactant in a composition implicitly means that the said composition has at least potentially cleansing/cleaning properties. Furthermore, the term "cleansing" is not considered to be a distinguishing feature by the EPC's.
 - 2.2 The subject-matter of present claims 1 to 3, 5 to 6 and 8 to 9 can therefore not be considered to be novel contrary to the requirements of Article 33(2) PCT.
3. The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claims 1 to 10 does not involve an inventive step in the sense of Article 33(3)PCT.
 - 3.1 The problem the applicant wished to solve with the present application is to provide cleansing composition based on oily substances having low irritation properties. The applicant solves his technical problem with the choice of the surfactant to be used in the composition; this surfactant being an N-acylated amino acid.
 - 3.2 Documents D2, D3 D3, which are concerned with cleansing cosmetic compositions,

are considered to be the most relevant state of the art for the subject matter of claims 1 to 10

Actually document D2 discloses (cf. page 1 lines 4 to 32, page 3 lines 1 to 26, page 4 lines 15 to 29 and examples) compositions containing as soothing agent N-acylated amino acid or proteins, particularly lauroyl glutamate, in an aqueous medium, document D3 (cf. page 2 lines 5 to 25, page 4 line 15 to page 5 line 8, page 7 line 32 to page 8 line 30 and examples) skin or hair care compositions containing capryloyl glutamate or capryloyl hydrolysate of wheat/rice proteins as hydrating agent, in an aqueous medium, and document D4 (cf.)page 3 lines 15 to 36, page 3 line 14 to page 5 line 22 and examples) conditioning shampoo compositions containing an anionic surfactant, which is an N-acylated amino acid, like N-acyl-L-glutamate and sodium lauroyl sarcosinate, in an aqueous medium.

- 3.3 The subject-matter of the present application differs from the disclosure of documents D2 to D4 in that the cleansing compositions contain mor than 10% water.
- 3.4 Cleansing compositions based on oily substances are known from the prior art (as indicated by the applicant in the description page 3).

An improvement in the tolerability of the present composition over the compositions described in documents D1 to D4 has not been shown, i.e a lower irritation of the skin or damage of the hair with a composition based on an N-acylated amino acid in an oily medium should therefore ~~should therefore~~ be compared to a composition based on the same N-acylated amino acid but in an aqueous medium.

- 3.5 The Applicant also disclosed that compositions based on oily substances are difficult to formulate, because of the poor solubility and low foaming capacities. An improvement over commonly known oily-based compositions has also not been shown in the present application.
- 3.6 The subject matter of present claims 1 to 10 does therefore not involve an inventive step in the sense of Article 33(3)PCT.